

## **R E M A R K S**

Entry of this Amendment and reconsideration of this application as amended are respectfully requested.

Claims 1-4, 6-14, 16-22, 34-43 and new claims 44 and 45 are pending in this application. Claims 23-32 are cancelled. Claims 5, 15 and 33 are withdrawn from consideration in view of the earlier election of species requirement.

Claims 1-4, 6, 9, 12-14, 16, 17, 39 and 42 are amended. Unless an argument is made below in support of the patentability of each of these claims over the cited prior art, the changes to these claims do not relate to patentability.

### **Election/Restriction**

Claims 5, 15 and 33 are withdrawn from consideration in view of the earlier election of species requirement. It is respectfully requested that these claims be re-joined with the elected claims if claims 1 and 13 are found to be allowable in a form generic to the embodiment set forth in these claim.

### **Claim Rejections-35 U.S.C. 102**

Claims 1-4, 6-14, 16-22 and 34-43 were rejected under 35 U.S.C. 102(b) as being anticipated by Takami et al. (U.S. Pat. No. 6,402,688).

The Examiner's rejection is respectfully traversed in view of changes to independent claims 1 and 13.

Claims 1 and 13 are amended to change the term "unitary" to the phrase "single member". As described in the specification, the body in various forms can be molded in one piece (see page 4, lines 7-9). The one-piece construction provides a single member or, as previously claimed, a unitary member. Use of the term "unitary" was intended to convey that proximal, expanded and distal portions of the body are all part of the one-piece construction. In view of the Examiner's interpretation of the claims to include a distal portion having arms which are

extremely distant and entirely separate from the proximal portion, the term "unitary" has been replaced by the phrase "single member", which is adequately supported by the recitation of the body having a one-piece construction. Moreover, new claim 45 is presented wherein the body is described as being monolithic, again conveying the existence of a single component.

Claim 1 is also amended to recite that the expanded portion of the body, interposed between a proximal portion adapted for insertion into the patient's anus and a distal portion adapted to mate with an inflation pump, extends radially outward from the proximal portion around the entire periphery of the proximal portion. By radially outward, it is meant that the expanded portion extends outward in radial directions from the longitudinal axis of the proximal portion.

Claim 13 is also amended to recite that the insertion-limiting means for limiting insertion of a proximal portion of the body into the anus and occluding an opening of the anus comprise an expanded portion of the body including a circular portion having a largest diameter of the expanded portion and which extends radially outward from a longitudinal axis of the proximal portion beyond an outer periphery of the proximal portion around the entire periphery of the proximal portion.

As shown in Fig. 11, the expanded portion 100 includes a circular outer circumferential portion 100a which extends radially outward from the proximal portion 96 of body 94 around the entire periphery of the proximal portion 96. This radial outward extension is substantially uniform around the entire periphery of the proximal portion 96. As a result, a truncated conical surface 108a is formed extending outward from the proximal portion 96 to the outer circumferential portion 100a (see the specification at page 14, lines 3-13). A "truncated conical" surface is a surface in the form of the outer or inner surface of a cone, i.e., a geometric form having a circular base and extending on one side to a point at a top, which is cut off

at the top to provide the surface with a circular base and a circular top having a different diameter than the circular base. In this case, the circular base would be contiguous with the outer circumferential portion 100a and the circular top would be contiguous with the proximal portion 96.

A significant purpose of the expanded portion which extends radially outward from the proximal portion around the entire periphery of the proximal portion as set forth in claim 1 or includes a circular portion having a largest diameter and which extends radially outward from a longitudinal axis of the proximal portion beyond an outer periphery of the proximal portion around the entire periphery of the proximal portion as set forth in claim 13 is to completely surround the anus in order to form an effective, air-tight seal between the body and the anus.

Takami et al. does not disclose, teach or suggest a expanded portion of a single member, elastomeric body having the form set forth in claims 1 and 13.

Takami et al. shows an endoscope 20 which comprises a flexible videoscope 32, a forceps-inlet 17 arranged at a proximal end of the videoscope 32 through which air enters into the endoscope 20 and a forceps-outlet 19 arranged at a distal end of the video-scope 32 through which air exits from the endoscope 20. The Examiner considered the transition region between the forceps-inlet 17 and the forceps-outlet 19 to constitute an expanded portion ("the transition region between elements 19 and 17", Office Action at page 3).

There are several differences between the claimed embodiments of the invention and the endoscope of Takami et al.

First, in contrast to the embodiments in claims 1 and 13, the endoscope of Takami et al. is not a single member body but rather, as an endoscope, it is a complex device with multiple members or parts.

Second, the transition region between the forceps-inlet 17 and the forceps-outlet 19 does not extend radially outward around

the entire periphery of the distal end of the videoscope 32 but rather extends to a bottom side as clearly shown in Fig. 1. The transition region between the forceps-inlet 17 and the forceps-outlet 19 also does not include a circular portion having a largest diameter and which extends beyond an outer periphery of the distal end of the videoscope 32 around the entire periphery thereof but again extends to a bottom side as shown in Fig. 1. Accordingly, the transition region cannot form an effective, air-tight seal between the body and the anus if inserted into the anus since when the anal sphincter is lax, air will leak out around those portions of the circumference of the videoscope 32 where an enlarged transition region is not provided. Takami et al. does not suggest any modification to videoscope 32 of endoscope 20 to prevent leakage of air when the endoscope 20 is inserted into a patient's anus.

Since Takami et al. does not disclose all of the features of claims 1 and 13, it cannot anticipated the embodiments of the invention set forth in these claims or in claims 2-4, 6-12, 14, 16-22 and 33-43 which depend directly or indirectly upon claim 1 or claim 13. Moreover, Takami et al. does not disclose, teach or suggest all of the features of the dependent claims. For example, Takami et al. does not disclose that the distal end of the videoscope 32 has a rounded or tapered tip having a smaller cross-section than a remaining portion to facilitate insertion thereof into the anus as set forth in claims 2 and 16. Rather, as clearly shown in Fig. 1, the tip of the forceps-outlet 19 appears to have a larger cross-section than a remaining portion of the videoscope 32.

Takami et al. does not disclose that the transition region between the forceps-inlet 17 and the forceps-outlet 19 has a circular portion having a largest diameter and which extends beyond an outer periphery of the videoscope 32 around the entire periphery thereof, with truncated conical surfaces (as explained above) on either side of the largest diameter circular portion as

set forth in claim 3. As discussed above, there is no circular portion in the transition region which extends beyond the periphery of the videoscope 32 around its entire periphery so that there cannot be any truncated conical surfaces in Takami et al.

Takami et al. does not disclose that a distal portion of a single member body has two arms connected to an expanded portion and each defining a lumen and an opening at an end opposite the expanded portion as set forth in claims 6 and 14. Rather, the endoscope 20, as illustrated, appears to have only a single lumen at the distal end of the videoscope 32, i.e., the lumen around which forceps-inlet 17 is arranged. The Examiner referred to first and second arms AT7 and AT8 which are shown in Fig. 3 of Takami et al. However, these "arms" are not part of a distal portion of a single member body but rather it should be noted that Fig. 3 does not even show the same "body" as shown in Fig. 1, i.e., endoscope 20 is not shown in Fig. 3 because Fig. 3 shows an air delivery unit 15 which provides air to the forceps-inlet 7 through a hose 16 (see Fig. 1). Arms AT7 and AT8 are thus situated within the air delivery unit 15 and cannot be considered part of a distal portion of a single member body.

Takami et al. does not disclose that a distal portion of a single member body has two arms, each having a lumen defining an opening and one of which has a central axis parallel to a common central axis of a proximal portion and an expanded portion of the body as set forth in claim 8. The Examiner referred to Fig. 1 of Takami et al. but the only arm with a lumen in Takami et al. is the forceps-inlet 17 which clearly does not have a central axis parallel to a central axis of the forceps-outlet 19.

Takami et al. does not disclose that a distal portion of a single member body has two arms, each defining a lumen as set forth in claim 9. The Examiner referred to first and second arms AT7 and AT8 which are shown in Fig. 3 of Takami et al. However, these "arms" are not part of a distal portion of a single member

body because arms AT7 and AT8 are situated within the air delivery unit 15 which is separate by several other members from the endoscope 20.

Takami et al. does not disclose a pressure relief valve arranged in a second lumen in a distal portion of a single member body for releasing air when a specific air pressure in the rectum is reached as set forth in claim 19. The Examiner referred to pressure regulating and relief valve 38 which is situated inside the air delivery unit 15 and is obviously not situated in a lumen of a distal portion of a single member body.

In view of the foregoing, it is respectfully submitted that the Examiner's rejection of claims 1-4, 6-14, 16-22 and 33-43 has been overcome and should be removed and that the present application is in condition for allowance.

#### New Claims

Claims 44 and 45 are added. A Form-2038 for payment of the fee of \$50.00 for presentation of these new claims is enclosed.

Claims 44 and 45 are directed to the elected embodiment and supported by the disclosure as originally filed. As such, no new matter is introduced by the presentation of claims 44 and 45.

An early and favorable action on the merits of the invention is earnestly solicited.

Respectfully submitted,

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